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Safety assessment of the process 'RecyPET Hungária', based on RecyPET Hungária technology, used to recycle post-consumer PET into food contact materials

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Abstract

The EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP) assessed the safety of the recycling process RecyPET Hungária (EU register number RECYC0146). The input is hot caustic washed and dried poly(ethylene terephthalate) (PET) flakes originating from collected post-consumer PET containers, containing no more than 5% of PET from non-food applications. The flakes are dried and extruded. The output of the extrusion step is cut into pellets in an underwater chamber and then recrystallised. The crystallised pellets may then be fed into a solid-state polycondensation (SSP) reactor. The recycled plastic is intended for manufacture of bottles for soft drinks or water. The applicant provided a challenge test, but the flakes contaminated with the surrogates and the pellets obtained after extrusion and crystallisation were extracted with *n*-hexane without showing sufficient recovery. The Panel considered the extraction as unreliable and could therefore not conclude on the efficiency of the decontamination process. Furthermore, the flow charts provided by the applicant did not enable a clear identification of the steps relevant for the decontamination efficiency, and no sufficiently clear overview of the operational parameters of the steps of the process and the challenge test was provided. Without this information, a proper safety evaluation could not be performed. The Panel concluded that the process RecyPET Hungária is not sufficiently characterised and the applicant has not demonstrated in an adequately performed challenge test or by other appropriate evidence that the recycling process RecyPET Hungária is able to reduce contamination of the PET input to a concentration that does not pose a risk to human health.

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Recycled plastic materials and articles shall only be placed on the market if they contain recycled plastic obtained from an authorised recycling process. Before a recycling process is authorised, EFSA's opinion on its safety is required. This procedure has been established in Article 5 of Regulation (EC) No 282/2008¹ of the Commission of 27 March 2008 on recycled plastic materials intended to come into contact with foods and Articles 8 and 9 of Regulation (EC) No 1935/2004² of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food.

According to this procedure, the industry submits applications to the Member States Competent Authorities which transmit the applications to the European Food Safety Authority (EFSA) for evaluation.

In this case, EFSA received from the National Food Chain Safety Office, Hungary, an application for evaluation of the recycling process RecyPET Hungária, European Union (EU) register No RECYC0146. The request has been registered in EFSA's register of received questions under the number EFSA-Q-2017-00092. The dossier was submitted on behalf of RecyPET Hungária Ltd., Hungary.

According to Article 5 of Regulation (EC) No 282/2008 of the Commission of 27 March 2008 on recycled plastic materials intended to come into contact with foods, EFSA is required to carry out risk assessments on the risks originating from the migration of substances from recycled food contact plastic materials and articles into food and deliver a scientific opinion on the recycling process examined.

According to Article 4 of Regulation (EC) No 282/2008, EFSA will evaluate whether it has been demonstrated in a challenge test, or by other appropriate scientific evidence, that the recycling process RecyPET Hungária is able to reduce the contamination of the plastic input to a concentration that does not pose a risk to human health. The poly(ethylene terephthalate) (PET) materials and articles used as input of the process as well as the conditions of use of the recycled PET make part of this evaluation.

2. Data and methodologies

2.1. Data

The applicant has submitted a technical dossier following the 'EFSA guidelines for the submission of an application for the safety evaluation of a recycling process to produce recycled plastics intended to be used for the manufacture of materials and articles in contact with food, prior to its authorisation' (EFSA, 2008). Applications shall be submitted in accordance with Article 5 of the Regulation (EC) No 282/2008.

Additional information was sought from the applicant during the assessment process in response to a request from EFSA sent on 12 July 2017 and 20 December 2017, and replies were provided respectively (see 'Documentation provided to EFSA').

Following the request by the Working Group a technical hearing was held with the applicant on 14 May 2018.³ After this hearing, additional information was sought again from the applicant on 4 June 2018 and a reply was provided (see 'Documentation provided to EFSA').

The following information on the recycling process was provided by the applicant and used for the evaluation:

- General information:
 - general description,
 - existing authorisations,
- Specific information:
 - recycling process,
 - characterisation of the input,
 - determination of the decontamination efficiency of the recycling process,
 - characterisation of the recycled plastic,

¹ Regulation (EC) No 282/2008 of the European parliament and of the council of 27 March 2008 on recycled plastic materials and articles intended to come into contact with foods and amending Regulation (EC) No 2023/2006. OJ L 86, 28.3.2008, p. 9–18.

² Regulation (EC) No 1935/2004 of the European parliament and of the council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC. OJ L 338, 13.11.2004, p. 4–17.

³ <https://www.efsa.europa.eu/sites/default/files/wgs/food-ingredients-and-packaging/recyclingplastics20172018.pdf>

- intended application in contact with food,
- compliance with the relevant provisions on food contact materials and articles,
- process analysis and evaluation,
- operating parameters.

2.2. Methodologies

The principles followed for the evaluation are described here. The risks associated with the use of recycled plastic materials and articles in contact with food come from the possible migration of chemicals into the food in amounts that would endanger human health. The quality of the input, the efficiency of the recycling process to remove contaminants, as well as the intended use of the recycled plastic, are crucial points for the risk assessment (see guidelines on recycling plastics: EFSA, 2008).

The criteria for the safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for the manufacture of materials and articles in contact with food are described in the scientific opinion developed by the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (EFSA CEF Panel, 2011). The principle of the evaluation is to apply the decontamination efficiency of a recycling technology or process, obtained from a challenge test with surrogate contaminants, to a reference contamination level for post-consumer PET, conservatively set at 3 mg/kg PET for contaminants resulting from possible misuse. The resulting residual concentration of each surrogate contaminant in recycled PET (C_{res}) is compared with a modelled concentration of the surrogate contaminants in PET (C_{mod}). This C_{mod} is calculated using generally recognised conservative migration models so that the related migration does not give rise to a dietary exposure exceeding 0.0025 µg/kg bodyweight (bw) per day (i.e. the human exposure threshold value for chemicals with structural alerts for genotoxicity), below which the risk to human health would be negligible. If the C_{res} is not higher than the C_{mod} , the recycled PET manufactured by such recycling process is not considered of safety concern for the defined conditions of use (EFSA CEF Panel, 2011).

The assessment was conducted in line with the principles described in the EFSA Guidance on transparency in the scientific aspects of risk assessment (EFSA, 2009) and considering the relevant guidance from the EFSA Scientific Committee.

3. Assessment

3.1. General information

According to the applicant, the recycling process RecyPET Hungária is intended to recycle food grade PET containers to produce recycled PET pellets. It is intended to use up to 30% recycled PET to manufacture new food packaging articles. These final materials and articles, i.e. bottles, are intended to be used in direct contact with soft drinks and water for long-term storage at room temperature.

3.2. Description of the process

3.2.1. General description

The recycling process RecyPET Hungária produces recycled PET pellets from PET containers coming from post-consumer collection systems (kerbside and deposit systems).

The recycling process comprises the following steps that are essential for the evaluation of the decontamination efficiency:

Input

Post-consumer PET containers are sorted, ground and processed into hot caustic washed and dried flakes, which are used as input of the process.

Decontamination and production of recycled PET material

- The flakes are dried and inspected by a metal separator.
- The flakes are extruded at high temperature partly under vacuum and then crystallised.
- The pellets may be further treated in a solid-state polycondensation (SSP) reactor. This step is optional.

Recycled PET pellets, the final product of the process, are checked against technical requirements on intrinsic viscosity, composition of colour of the pellets and moisture. They are intended to be

converted by other companies into recycled articles used for long-term storage at room temperature, i.e. bottles for water and soft drinks.

The information on the process provided to EFSA is incomplete and inconsistent.

3.2.2. Characterisation of the input

According to the applicant, the input material for the recycling process RecyPET Hungária consists of hot caustic washed and dried flakes obtained from PET containers, mainly bottles, previously used for food packaging, from post-consumer collection systems (kerbside and deposit systems). A small fraction may originate from non-food applications, such as soap bottles, mouthwash bottles, kitchen hygiene bottles, etc. According to information from the applicant, the amount of this non-food container fraction depends on the collection system and will be below 5%.

Technical data for the washed and dried flakes are provided, such as information on residual content of poly(vinyl chloride) (PVC), glue, polyolefins (polypropylene, polyethylene), metals, other plastics (e.g. polyamide, polycarbonate), coloured PET, PET of different colour, humidity, other pollutants and bad quality flakes (see Appendix A).

3.3. RecyPET Hungária technology

3.3.1. Description of the main steps

Despite a description of the process with many details, no appropriate general scheme of the RecyPET Hungária process was provided that would enable to perform the safety assessment according to the EFSA Guidelines.

Post-consumer PET containers, mainly bottles, are processed by the applicant into hot caustic washed and dried flakes, followed by:

- **Drying:** In this step, the flakes are dried at high temperature for a predefined residence time.
- **Extrusion, underwater granulation and crystallisation:** The flakes from the previous step are fed into an extruder consisting of a 12-screw ring system at high temperature partly under vacuum. The thin leads produced by the extrusion process are further processed in an underwater chamber where they are cut to pellets. The pellets are recrystallised at a higher temperature.
- **SSP:** The pellets may be introduced into the SSP reactor. This step is optional.

Since the information provided to EFSA on the process relevant for establishing the decontamination efficiency was incomplete and inconsistent, the Panel was unable to derive an adequate description of the critical steps of the RecyPET Hungária process.

3.3.2. Decontamination efficiency of the recycling process

To demonstrate the decontamination efficiency of the recycling process RecyPET Hungária, a challenge test was submitted to EFSA that was performed at the RecyPET Hungária facilities.

PET flakes were contaminated with toluene, isopropanol, chloroform, phenylcyclohexane, benzophenone, methyl salicylate, limonene, chlorobenzene, methyl stearate and *o*-cresol, selected as surrogate contaminants in agreement with EFSA guidelines and in accordance with the recommendations of the US Food and Drug Administration. The surrogates include different molecular weights and polarities to cover possible chemical classes of contaminants of concern and were demonstrated to be suitable to monitor the behaviour of PET during recycling (EFSA, 2008).

For the preparation of the contaminated PET flakes, 120 kg blue PET flakes were soaked in a *n*-hexane solution containing the surrogates and stored for 21 days at 38°C, with daily agitation. The surrogate solution was decanted and PET flakes were air-dried on a polymeric foil. The 120 kg of blue flakes were mixed with 600 kg of uncontaminated transparent flakes. The mixed flakes were hot washed and dried. The concentration of surrogates in the contaminated flakes was determined, by extraction with *n*-hexane.

The RecyPET Hungária process was challenged in a plant scale experiment, using the mixture of contaminated and non-contaminated flakes, as described above. The flakes were dried, extruded and crystallised. For analysis, samples were taken before drying and after extrusion and crystallisation. The samples (flakes then pellets) were analysed for the concentrations of surrogates. The SSP step was not included in the challenge test, as it was stated to be optional, depending on the intrinsic viscosity required.

The decontamination efficiency of the process was calculated taking into account the amount of the surrogates detected in washed flakes and pellets after extrusion and crystallisation, using *n*-hexane as a solvent for extraction, thermostating the samples in an ultrasonic basin for 30 min at 40°C. When not detected, the limit of detection was considered for the calculation of the decontamination efficiency. The results are summarised below in Table 1.

Table 1: Efficiency of the decontamination of the RecyPET Hungária technology in the challenge test, calculated from the data provided by the applicant

Surrogates	Concentration of surrogates before drying (mg/kg PET)	Concentration of surrogates after crystallisation (mg/kg PET)	Decontamination efficiency (%)
Toluene	583.6	2.33	99.6
Iso-propanol	387.8	< 1.00	> 99.7
Chloroform	673.5	< 1.00	> 99.9
Phenylcyclohexane	56.4	< 1.00	> 98.2
Benzophenone	116.3	< 1.00	> 99.1
Methyl salicylate	129.8	< 1.00	> 99.2
Limonene	10.9	< 1.00	> 90.8
Chlorbenzol	108.1	< 1.00	> 99.1
Methyl stearate	54.7	11.4	79.2
<i>o</i> -Cresol	65.8	2.78	95.8

3.4. Discussion

This evaluation focuses on the chemical safety of the final pellets.

Technical data, such as information on residual content of poly(vinyl chloride) (PVC), glue, polyolefins, metals, other plastics, coloured PET, PET of different colour, humidity, other pollutants and bad quality flakes, were provided for the input materials (washed and dried flakes) for the submitted recycling process. The input materials are produced from PET containers previously used for food packaging collected through post-consumer collection systems. However, a small fraction may originate from non-food applications, such as soap bottles, mouthwash bottles, kitchen hygiene bottles, etc. According to the applicant, the proportion of this non-food container fraction depends on the collection system and the process is managed in such a way that in the input stream of the recycling process this amount will be lower than 5%, as recommended by the EFSA CEF Panel in its 'Scientific opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact with food' (EFSA CEF Panel, 2011).

The Panel identified inconsistencies and discrepancies in the information provided by the applicant, and despite several requests for clarification, fundamental issues were not satisfactorily addressed, in particular:

- 1) The completeness of the extraction of the surrogates from the flakes and the pellets has not been demonstrated by the applicant. The Panel considered that *n*-hexane is not the appropriate solvent for extraction of PET (insufficient swelling). The yield of the extraction from the surface contamination of the flakes would be higher than that from inside the pellets. This would result in a higher decontamination efficiency than really achieved.
- 2) The flow charts provided by the applicant were not considered adequate, because the steps of the process relevant for the decontamination efficiency could not clearly be identified.
- 3) A clear overview of the operational parameters of the steps of the process and the challenge test was not provided.

Overall, the dossier does not satisfy the requirements of the EFSA guidelines, because the Panel considered the challenge test provided by the applicant as unreliable and not suitable for determining the cleaning efficiency of the process. Moreover, the data provided did not allow the identification of the critical parameters for the relevant steps of the process. Without this information, a proper safety evaluation could not be performed.

Information on these points was requested to the applicant several times, but the respective answers did not fully address the concerns raised by the CEP Panel. Therefore the evaluation of the RecyPET Hungária recycling process was concluded on the basis of the information provided.

4. Conclusions

The Panel concluded that the process RecyPET Hungária is not adequately characterised. Based on the information submitted to EFSA, the applicant has not demonstrated in an adequately performed challenge test or by other appropriate evidence that the recycling process RecyPET Hungária is able to reduce contamination of the PET flakes input to a concentration that does not pose a risk to human health.

Documentation provided to EFSA

- 1) Dossier "RecyPET Hungária". February 2017. Submitted on behalf of RecyPet Hungária Ltd.
- 2) Additional data. August 2017. Submitted by RecyPet Hungária Ltd.
- 3) Additional data. February 2018. Submitted by RecyPet Hungária Ltd.
- 4) Additional data. September 2018. Submitted by RecyPet Hungária Ltd.

References

- EFSA (European Food Safety Authority), 2008. Guidelines for the submission of an application for safety evaluation by the EFSA of a recycling process to produce recycled plastics intended to be used for manufacture of materials and articles in contact with food, prior to its authorisation. EFSA Journal 2008;6(7):717, 12 pp. <https://doi.org/10.2903/j.efsa.2008.717>
- EFSA (European Food Safety Authority), 2009. Guidance of the Scientific Committee on transparency in the scientific aspects of risk assessments carried out by EFSA. Part 2: general principles. EFSA Journal 2009; 7(5):1051, 22 pp. <https://doi.org/10.2903/j.efsa.2009.1051>
- EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2011. Scientific opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact with food. EFSA Journal 2011;9(7):2184, 25 pp. <https://doi.org/10.2903/j.efsa.2011.2184>

Abbreviations

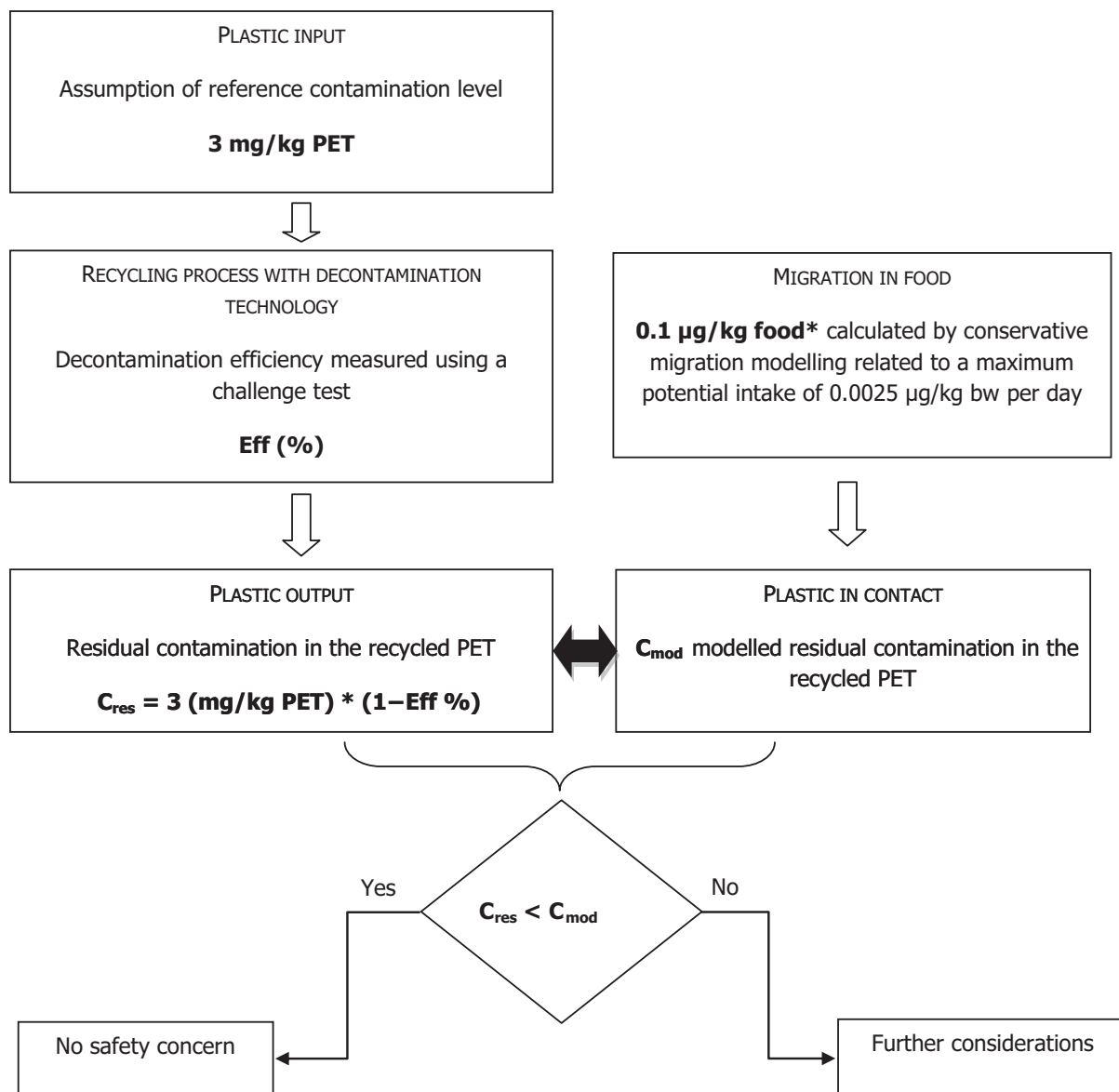
bw	body weight
CEF Panel	Food Contact Materials, Enzymes, Flavourings and Processing Aids
CEP Panel	Food Contact Materials, Enzymes and Processing Aids
C _{mod}	modelled concentration in PET
C _{res}	residual concentrations in PET
PET	poly(ethylene terephthalate)
PVC	poly(vinyl chloride)
SSP	solid-state polycondensation

Appendix A – Technical data of the washed flakes as provided by the applicant

Parameter	Value
Moisture max.	$\leq 1.0\%$
PET of different colour max.	$\leq 3\%$
Coloured PET max.	$\leq 1\%$
Other pollutants max.	$\leq 40 \text{ mg/kg}$
PVC max.	$\leq 100 \text{ mg/kg}$
Glue max.	$\leq 0.5\%$
Polyolefins (polypropylene, polyethylene) max.	$\leq 30 \text{ mg/kg}$
Other plastics (e.g. polyamide, polycarbonate) max.	$\leq 150 \text{ mg/kg}$
Metals max.	$\leq 40 \text{ mg/kg}$
Bad quality flakes max.	$\leq 0.5\%$

PET: poly(ethylene terephthalate); PVC: poly(vinyl chloride).

Appendix B – Relationship between the key parameters for the evaluation scheme (EFSA CEF Panel, 2011)



*Default scenario (infant). For adults and toddlers, the migration criterion will be 0.75 and 0.15 µg/kg food, respectively.